

We claim:

1. A platelet concentrate unit comprising
a sealed container,
a platelet concentrate mixture carried in the
sealed container, the platelet concentrate mixture
comprising a platelet concentrate volume, a plasma
volume, and a synthetic platelet additive solution
volume,

5 the platelet concentrate volume and the plasma
volume having been collected from a unit of whole blood
10 drawn from an individual donor and processed by
centrifugation in a sterile, closed blood collection
system which included the sealed container, and

15 the synthetic platelet additive solution
volume having been mixed with the platelet concentrate
volume and the plasma volume in the sterile, closed blood
collection system, the synthetic platelet additive
solution volume including ingredients that condition the
platelet concentrate mixture for pathogen inactivation in
the presence of a selected pathogen inactivating
20 compound.

2. A platelet concentrate unit according to
claim 1

5 wherein the sealed container includes an
appendage sized and configured for coupling to tubing to
transfer the platelet concentrate mixture from the sealed
container to a selected destination.

3. A platelet concentrate unit according to
claim 2

wherein the appendage couples to the tubing to
form an essentially sterile connection.

4. A platelet concentrate unit according to
claim 1

wherein the platelet concentrate volume is in
a leukocyte-reduced condition as a result of filtration

RECEIVED
U.S. PATENT AND TRADEMARK OFFICE

5 in the sterile, closed blood collection system.

5. A platelet concentrate unit according to
claim 1

5 wherein the ingredients comprise an aqueous
solution including sodium chloride, sodium citrate,
sodium acetate, and sodium phosphate.

6. A platelet concentrate unit according to
claim 1

5 wherein the selected pathogen inactivating
compound is selected from a group comprising psoralens,
methylene blue, dimethyl-methylene blue, riboflavin, or
PEN 110, or combinations thereof.

7. A platelet pooling assembly comprising
a manifold sized and configured to convey
multiple platelet concentrate mixtures from a plurality
of platelet concentrate units as defined in claim 1, and
5 a container coupled to the manifold for
pooling the multiple platelet concentrate mixtures.

8. A platelet pooling assembly according to
claim 7

5 wherein the container includes an appendage
sized and configured for coupling the container to a
source of the selected pathogen inactivating compound.

9. A platelet pooling assembly according to
claim 7

further including a filter for removing
leukocytes from platelets.

10. A platelet pooling assembly comprising
a manifold sized and configured to convey
multiple platelet concentrate mixtures from a plurality
of a platelet concentrate units as defined in claim 1,
5 and

a first container coupled to the manifold for
pooling the multiple platelet concentrate mixtures, and
a second container coupled to the first

10000325120000

10 container to receive the multiple platelet concentrate mixtures after centrifugation in the first container to remove residual red blood cells.

11. A platelet pooling assembly according to claim 10

5 wherein the second container includes an appendage sized and configured for coupling the second container to a source of the selected pathogen inactivating compound.

12. A platelet pooling assembly according to claim 10

further including a filter for removing leukocytes from platelets.

13. A platelet pooling assembly comprising a first container for receiving a concentration of platelets, and

5 tubing to the first container to receive the concentration of platelets after centrifugation in the first container to remove residual red blood cells.

14. A platelet pooling assembly according to claim 13

5 wherein the first container includes a region of reduced volume to collect the residual red blood cells.

15. A platelet pooling assembly according to claim 13

5 wherein the first container includes a region of reduced volume to concentrate the residual red blood cells.

16. A platelet pooling assembly according to claim 13

5 further including a third container integrally coupled by tubing to the first container to receive the separated residual red blood cells.

17. A platelet pooling assembly according to
claim 16

further including a one-way valve in the tubing between the first and third container to resist fluid flow from the third container toward the first container.

18. A platelet pooling assembly according to
claim 13

wherein the tubing carries an in-line filter to remove leukocytes from platelets.

19. A platelet pooling assembly comprising a manifold sized and configured to receive multiple platelet concentrate units that have centrifugally separated from individual random donors, the manifold further including a site to receive a synthetic platelet additive solution for mixing with the multiple platelet concentrate units, and

a container coupled to the manifold for pooling a mixture of the multiple platelet concentrate units and the synthetic platelet additive solution.

20. A platelet pooling assembly according to
claim 19

wherein the synthetic platelet additive solution volume includes ingredients that condition the multiple platelet concentrate units for pathogen inactivation in the presence of a selected pathogen inactivating compound.

21. A platelet pooling assembly according to
claim 20

wherein the ingredients comprise an aqueous solution including sodium chloride, sodium citrate, sodium acetate, and sodium phosphate.

22. A platelet concentrate unit according to
claim 20

wherein the selected pathogen inactivating

5 compound is selected from a group comprising psoralens, methylene blue, dimethyl-methylene blue, riboflavin, or PEN 110, or combinations thereof.

23. A platelet pooling assembly according to claim 20

5 wherein the container includes an appendage sized and configured for coupling the container to a source of the selected pathogen inactivating compound.

24. A platelet pooling assembly according to claim 19

further including a filter for removing leukocytes from platelets.

25. A platelet pooling assembly according to claim 19

5 further including a second container coupled by tubing to the first container to receive the mixture after separation of residual red blood cells.

26. A platelet pooling assembly according to claim 25

further including a filter for removing leukocytes from platelets.

27. A manual blood collection system comprising

5 a primary container sized and configured to hold a unit of whole blood drawn from an individual donor for centrifugal separation,

a platelet unit container sized and configured to hold a platelet concentrate and a first volume of plasma centrifugally separated from the unit of whole blood,

10 a plasma unit container sized and configured to hold a second volume of plasma centrifugally separated from the unit of whole blood,

an auxiliary container sized and configured to hold a synthetic platelet additive solution that, when

SEARCHED
INDEXED
SERIALIZED
FILED

15 mixed with the platelet concentrate and first volume of
plasma, creates a platelet concentrate mixture, the
synthetic platelet additive solution including
ingredients that condition the platelet concentrate
mixture for pathogen inactivation in the presence of a
20 selected pathogen inactivating compound, and

tubing integrally coupling the primary
container, the platelet unit container, the plasma unit
container, and the auxiliary container to form a sterile,
closed blood processing system.

28. A manual blood collection system
according to claim 27

wherein, after processing in the sterile,
closed blood processing system, the platelet concentrate
5 mixture is held by the platelet unit container.

29. A manual blood collection system
according to claim 28

wherein the platelet unit container includes
an appendage sized and configured for coupling to
5 transfer tubing to transfer the platelet concentrate
mixture from the platelet unit container to a selected
destination.

30. A manual blood collection system
according to claim 29

wherein the appendage couples to the transfer
tubing to form an essentially sterile connection.

31. A manual blood collection system
according to claim 27

wherein, after processing in the sterile,
closed blood processing system, the platelet concentrate
5 mixture is held by the auxiliary container.

32. A manual blood collection system
according to claim 31

wherein the auxiliary container includes an
appendage sized and configured for coupling to transfer

PCT/US2008/033266

5 tubing to transfer the platelet concentrate mixture from the auxiliary container to a selected destination.

33. A manual blood collection system according to claim 32

wherein the appendage couples to the transfer tubing to form an essentially sterile connection.

34. A manual blood collection system according to claim 27

wherein the tubing carries an in-line filter to remove leukocytes from platelets.

35. A manual blood collection system according to claim 27

wherein the ingredients comprise an aqueous solution including sodium chloride, sodium citrate, sodium acetate, and sodium phosphate.

36. A manual blood collection system according to claim 27

wherein the selected pathogen inactivating compound is selected from a group comprising psoralens, 5 methylene blue, dimethyl-methylene blue, riboflavin, or PEN 110, or combinations thereof.

37. A manual blood collection system according to claim 27

further including a red blood cell unit container sized and configured to hold red blood cells 5 centrifugally separated from the unit of whole blood, and

wherein the tubing integrally couples the primary container, the platelet unit container, the plasma unit container, the red blood cell unit container, and the auxiliary container to form a sterile, closed 10 blood processing system.

38. A manual blood collection system according to claim 37

wherein the plasma unit container carries an additive solution for mixing with red blood cells.

39. A manual blood collection system according to claim 37

5 further including a container holding a synthetic red blood cell additive solution including ingredients that condition the red blood cells for pathogen inactivation in the presence of a selected pathogen inactivating compound.

40. A manual blood collection system according to claim 39

wherein the ingredients include sodium citrate, sodium phosphate, adenine, and mannitol.

41. A manual blood collection system according to claim 39

wherein the ingredients further include dextrose.

42. A manual blood collection system according to claim 37

wherein the tubing carries an in-line filter to remove leukocytes from red blood cells.

43. A system for collecting a pooled therapeutic platelet unit conditioned for pathogen inactivation from random donor platelet units comprising

means for collecting from a unit of whole blood drawn from an individual donor and processed by centrifugation in a sterile, closed blood collection system, a random donor sterile platelet component unit that has been conditioned for pathogen inactivation by the mixing, in the sterile, closed blood processing system, of a prescribed platelet additive solution, and

means for pooling in a sterile, closed system a plurality of random donor sterile platelet component units to provide a pooled random donor sterile platelet component dose that is conditioned for pathogen inactivation due to the presence of the platelet additive solution.

44. A system according to claim 43
further including means for subjecting the
pooled random donor sterile platelet component dose to
closed system leukocyte filtration.

45. A system according to claim 43
further including means for subjecting the
random donor sterile platelet component unit to closed
system leukocyte filtration.

46. A system according to claim 43
further including means for mixing with the
pooled random donor sterile platelet component dose a
desired volume of a pathogen inactivating compound to
provide a treatment-ready pooled random donor dose.

47. A system according to claim 46
further including means for subjecting the
treatment-ready pooled random donor dose to pathogen
decontamination.

48. A system for collecting a pooled therapeutic platelet unit conditioned for pathogen inactivation from random donor platelet units comprising means for collecting from a unit of whole blood drawn from an individual donor and processed by centrifugation in a sterile, closed blood collection system, a random donor sterile platelet component unit, and

means for pooling in a sterile, closed system a plurality of random donor sterile platelet component units, while also mixing, in the sterile, closed system, a prescribed platelet additive solution, to provide a pooled random donor sterile platelet component dose that is conditioned for pathogen inactivation due to the presence of the platelet additive solution.

49. A system according to claim 48
further including means for subjecting the
pooled random donor sterile platelet component dose to

closed system leukocyte filtration.

50. A system according to claim 48 further including means for subjecting the random donor sterile platelet component unit to closed system leukocyte filtration.

51. A system according to claim 48 further including means for mixing with the pooled random donor sterile platelet component dose a desired volume of a pathogen inactivating compound to provide a treatment-ready pooled random donor dose.

52. A system according to claim 51 further including means for subjecting the treatment-ready pooled random donor dose to pathogen decontamination.

53. A method for collecting a random donor platelet unit conditioned for pathogen inactivation comprising the step of collecting from a unit of whole blood drawn from an individual donor and processed by centrifugation in a sterile, closed blood collection system, a random donor sterile platelet component unit that has been conditioned for pathogen inactivation by the mixing, in the sterile, closed blood processing system, of a prescribed platelet additive solution.

54. A method according to claim 53 further including the step of subjecting the random donor sterile platelet component unit to closed system leukocyte filtration.

55. A method according to claim 53 further including the step of collecting from the unit of whole blood in the sterile, closed blood processing system, at least one additional blood component.

56. A method for collecting a pooled therapeutic platelet unit conditioned for pathogen inactivation from random donor platelet units comprising

the steps of

5 collecting from a unit of whole blood drawn
from an individual donor and processed by centrifugation
in a sterile, closed blood collection system, a random
donor sterile platelet component unit that has been
conditioned for pathogen inactivation by the mixing, in
10 the sterile, closed blood processing system, of a
prescribed platelet additive solution, and

15 pooling in a sterile, closed system a
plurality of random donor sterile platelet component
units to provide a pooled random donor sterile platelet
component dose that is conditioned for pathogen
inactivation due to the presence of the platelet additive
solution.

57. A method according to claim 56

 further including the step of subjecting the
pooled random donor sterile platelet component dose to
closed system leukocyte filtration.

58. A method according to claim 56

 further including the step of subjecting the
random donor sterile platelet component unit to closed
system leukocyte filtration.

59. A method according to claim 56

 further including the step of mixing with the
pooled random donor sterile platelet component dose a
desired volume of a pathogen inactivating compound to
5 provide a treatment-ready pooled random donor dose.

60. A method according to claim 59

 further including the step of subjecting the
treatment-ready pooled random donor dose to pathogen
decontamination.

61. A method for collecting a pooled
therapeutic platelet unit conditioned for pathogen
inactivation from random donor platelet units comprising
the steps of

5 collecting from a unit of whole blood drawn
from an individual donor and processed by centrifugation
in a sterile, closed blood collection system, a random
donor sterile platelet component unit, and

10 pooling in a sterile, closed system a
plurality of random donor sterile platelet component
units, while also mixing, in the sterile, closed system,
a prescribed platelet additive solution, to provide a
pooled random donor sterile platelet component dose that
is conditioned for pathogen inactivation due to the
15 presence of the platelet additive solution.

62. A method according to claim 61
further including the step of subjecting the
pooled random donor sterile platelet component dose to
closed system leukocyte filtration.

63. A method according to claim 61
further including the step of subjecting the
random donor sterile platelet component unit to closed
system leukocyte filtration.

64. A method according to claim 61
further including the step of mixing with the
pooled random donor sterile platelet component dose a
desired volume of a pathogen inactivating compound to
5 provide a treatment-ready pooled random donor dose.

65. A method according to claim 64
further including the step of subjecting the
treatment-ready pooled random donor dose to pathogen
decontamination.